UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INSULIN PRICING LITIGATION	**CASE NO. 2:23-md-03080 (BRM)(RLS)** **MDL No. 3080**
	JUDGE BRIAN R. MARTINOTTI
THIS DOCUMENT RELATES TO: ***Lake County, Illinois v. Eli Lilly, et al.*** **Case No. 2:23-cv-08487**	JUDGE RUKHSANAH L. SINGH
	AMENDED COMPLAINT **APPENDIX A:** **GLOSSARY**

This Glossary is intended as a convenient general reference for reading this Complaint. As part of the Insulin Pricing Scheme, contractual definitions often vary from the industry definitions and definitions used here. Regulatory definitions may vary from the definitions used here and from one another. Some terms may carry different meanings outside the pharmacy benefit context. All terms are defined in the pharmacy benefit context. Capitalized terms within definitions are themselves defined in the glossary. The term "drug" used in the definitions may include biologics. Some defined terms do not appear in the Complaint, but appear in cited documents, regulations, or other related literature.

Administrative Fees. In the context of a PBM-Payor contract, claims-processing fees charged after adjudication of a prescription drug claim.

Authorized Generic. An approved Brand Name Drug (or Biologic) marketed without the brand name on the label.

Average Manufacturer Price (AMP). The average price paid by wholesalers for drugs distributed to retail or paid by pharmacies directly to a manufacturer, net of price concessions (such as prompt-pay discounts) and various fees paid by manufacturers to wholesalers).

Average Wholesale Price (AWP). A drug-pricing benchmark reflecting the average price paid by a retailer to a pharmacy wholesaler. AWP does not represent actual market prices, but often is the benchmark from which costs or fees are determined.

Beneficiary. An individual member of a group health or group prescription drug plan, e.g., Lake County employees, dependents, and retirees.

Best Price. The lowest price made available at a given time point from a manufacturer to another (e.g., to a wholesaler, retailer, or government entity).

Biologic. Manufactured insulins derived from living organisms. The broader category of Biologics (biological products) includes vaccines, gene therapies, and other products derived from living material such as cells or tissues. They typically are large, complex molecules, as distinguished from small-molecule drugs. For more detail, see FDA's *Biological Product Definitions*, https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf.

Biosimilar. A highly similar copy of a Biologic that has no clinically meaningful differences from the Biologic serving as the "reference product." Biosimilars are conceptually similar to Generic Drugs. Both are approved through (different) abbreviated and less expensive approval pathways. *Cf.* Biologic.

Brand Name Drug. A drug marketed under a proprietary, trademark-protected name.

Clinical Fees. Amounts paid by Payors/Plans to PBMs for the management of clinical programs not included in general Administrative Fees, e.g., implementation and oversight of Prior Authorizations, Step Therapy, and the like.

Co-pay/Co-payment. The contribution made by a Beneficiary toward the cost of a drug or treatment. Co-pays are fixed costs (e.g., $10 for a particular drug), whereas co-insurance is paid as a percentage of the cost of a drug or treatment (e.g., and 80/20 plan in which insureds are responsible for 20% of costs). Co-pays may apply before or after the Deductible is reached, but co-insurance applies only after the Deductible is reached.

Deductible. The amount of money a Beneficiary pays out-of-pocket before insurance or self-insured coverage begins to pay.

DIR (Direct and Indirect Remuneration). As simplified from the definition in the Medicare Part D DIR Reporting Guidance for 2021: Any form of price concession the plan sponsor or PBM receives from any source (including manufacturers, pharmacies, enrollees, or any other person or entity), either directly or indirectly, including discounts, chargebacks, rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in kind, free or reduced-price services, grants, legal judgment amounts, settlement amounts from lawsuits or other legal action, and other price concessions or similar benefits. It also includes price concessions from, and additional contingent payments to, network pharmacies that cannot reasonably be determined at the point of sale.

Dispensing Fees. Costs incurred at the point of sale in addition to the Ingredient Cost of a drug. A Payor's drug cost often is calculated based on Ingredient Cost + Dispensing Fee – Copay – Rebate (if applicable). In the Medicare Part D context, dispensing fees are defined in 42 CFR § 423.100.

Fee-For-Service (FFS). Arrangements by which PBMs (or others) pay providers directly for the delivered services or drugs.

Formulary. The list of drugs covered by a plan. Formularies generally employ tiered cost-sharing—the grouping of drugs into different cost-sharing levels, which incentivizes the use of particular drugs. Lower tiers ordinarily are associated with lower out-of-pocket costs.

Generic Drug. A copy of a Brand Name Drug that contains identical amounts of the same active ingredient. A Generic Drug is the same in dosage, safety, strength, how it is taken, quality, performance, and intended use as its brand-name counterpart.

Gross Cost. The full acquisition cost of a prescription drug. It often is used to refer to the price paid at the point of sale. *Cf.* Net Cost.

Ingredient Cost. The actual amount paid to a pharmacy for a prescription drug, not including the Dispensing Fee.

List Price. *See* Wholesale Acquisition Cost (WAC).

Maximum Allowable Cost (MAC). The maximum amount a Payor/Plan will be required to pay for a particular drug.

Medicaid Drug Rebate Program (MDRP). A program including Centers for Medicare & Medicaid Services (CMS), state Medicaid agencies, and manufacturers that offsets federal and state prescription drug costs for Medicaid patients via a prescription drug rebate. Medicaid Drug Rebate (MDR) amounts are determined in accordance with 42 C.F.R. § 447.509.

Multiple Source Drug. A drug for which there is at least one other available drug product that is considered equivalent (e.g., a generic equivalent). See 42 U.S.C § 1396r-8(k)(7) for a detailed technical definition. *Cf.* Single Source Drug.

Net Cost. The realized drug cost after the Gross Cost is reduced by any benefits gained from acquiring the drug, i.e., the cost of the drug after accounting for any rebates, discounts, or other price concessions associated with its purchase. *Cf.* Gross Cost.

Net Price. The price a manufacturer ultimately realizes, i.e., the list price less rebates, discounts, etc. (net sales divided by volume).

National Average Drug Acquisition Cost (NADAC). A national drug-pricing benchmark reflecting invoice prices paid by retail pharmacies for prescription and over-the-counter products.

National Drug Codes (NDCs). Unique three-part codes published by the FDA to identify drugs.

Non-Preferred Drug. *See* Preferred Drug.

Payor/Plan/Sponsor. In the context of this action, a self-insured entity providing prescription drug coverage to its Beneficiaries, e.g., Lake County.

PDP. Prescription Drug Plan, i.e., prescription drug coverage offered under a contract—here, a contract between a self-insured government entity (Lake County) and a PBM.

PDP Sponsor. A nongovernmental entity that is certified as meeting Medicare the requirements and standards for offering prescription drug coverage.

PMPM (Per Member Per Month). The dollar amount paid by a Payor/Plan in prescription drug costs each month for each plan member (Beneficiary), i.e., the monthly cost divided by the number of plan members. PMPM calculations often are based on Ingredient Cost.

Preferred Drug. A covered drug on a Formulary for which Beneficiary cost-sharing is lower and/or which may have fewer Utilization Restrictions than non-preferred drugs in the Formulary. A non-preferred drug may appear on the Formulary, but within a tier where there are more Utilization Restrictions, such as higher Co-pays. Similarly, there may be preferred or non-preferred pharmacies, with non-preferred pharmacies offering drugs at higher cost-sharing levels (i.e., higher Beneficiary or Payor/Plan costs).

Prior Authorization (PA). A type of Utilization Restriction requiring Beneficiaries to seek approval for a prescription drug as a condition coverage. Preferred Drugs generally have fewer Utilization Restrictions and Payors/Plans often pay PBMs clinical fees for implementing Utilization Restrictions like Prior Authorization.

Single Source Drug/Single Source Brand Drug. A drug manufactured by only one company. Single source drugs do not have generic equivalents. *Cf.* Multiple Source Drug.

Specialty Drug. Drugs manufactured to treat chronic, complex, or life-threatening conditions, e.g., chemotherapy agents and hemophilia drugs. Insulins are not routinely, if ever, listed as specialty drugs.

Spread Pricing. The difference between the payments made by a PBM to the pharmacy for a prescription and the amount it charges to the Payor/Plan for the same claim or, said differently, charging a Payor/Plan more than the PBM pays the pharmacy for a prescription.

Step Therapy. A type of Utilization Restriction under which drug therapy begins with the least expensive therapy. More expensive therapies are used only if the Beneficiary fails to respond to the first-line drug or upon Prior Authorization.

Utilization Restrictions. Restrictions placed on certain drugs within a Formulary to limit usage (e.g., Prior Authorization, Step Therapy, or limits on quantities that may be dispensed). These are sometimes called formulary restrictions, coverage restrictions, or utilization management tools.

Wholesale Acquisition Cost (WAC). The undiscounted price for a drug or biologic to wholesalers, distributors, or other direct purchasers as self-reported by the Manufacturer Defendants (aka "list price:"). *Cf.* Net Price.